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Operational experience and lessons learned on influenza vaccination post authorization safety studies

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In this session, Ms. Palucci will discuss conducting real world post-authorization studies and surveillance activity for vaccines, including those conducted under the interim EMA guidance for enhanced safety surveillance for seasonal influenza vaccines in the EU of April 2014. Assessment of the safety and effectiveness of seasonal and pandemic influenza vaccines as well as other newly introduced vaccines presents different considerations and challenges than for other medical products. Widespread use in healthy populations, including children, pregnant women and the elderly establishes high societal requirements for demonstrated benefit (effectiveness) and product safety. Challenges for surveillance include the need to monitor vaccine products that may differ in reactogenicity or other adverse effects between products or batches and the desire to obtain rapid assessment of product safety and assessment that may be available for evaluation in near real-time.

Biography

Ombretta Palucci is a Senior Director within Quintiles Real World and Late Phase team focusing in Real World Evidence generation. She is responsible to advice on the best strategy and operational approach to collect meaningful real world data. The last 8 years, she has been fully dedicated to observational studies including PASS, drug registry, disease registry and burden of illness studies. She is expert in addressing study implementation challenges in real world studies.

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